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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,331	05/04/2006	Yutaka Tokiwa	290753US0PCT	5709

22850 7590 10/26/2007

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/578,331	TOKIWA, YUTAKA	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on July 25, 2005, has been received and entered.

Claims 1-9 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation " ...having a molecular weight between approximately 47,00 to 56,000..." in claim 1 is indefinite because, from the way it is written it not clear which molecule has the claimed molecular weight, the enzyme or the polyhydroxyalkonate resin.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter.

Claim 9 is directed to "an actinomycete of the genus *Streptomyces*" and its qualities. *Streptomyces* is a naturally occurring bacterium and is not a "manufacture". The claim does not require any physical transformation of the bacteria. The claimed invention would impermissibly cover every substantial practical application of, and thereby preempt all use of a product of nature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (Antonie van Leeuwenhoek, March 2003, Vol. 183, pages 183-189).

Claim 6 is drawn to a method for degrading a polyhydroxyalkanoate (PHA) resin, which comprises causing the PHA resin to come into contact wit an actinomycete of the genus Streptomyces at 40°C to 55°C.

Kim et al. disclose a method for degrading a polyhydroxyalkanoate (PHA) resin, which comprises causing the PHA resin to come into contact with an actinomycete of the genus Streptomyces at 40°C to 55°C (see Abstract).

Kim et al. therefore clearly anticipated the claimed invention.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Mergaret et al. (Applied & Environmental Microbiology, 1993, Vol. 59, No. 10, p. 32388-3238).

Mergaret et al. disclose a method for degrading a polyhydroxyalkanoate (PHA) resin, which comprises causing the PHA resin to come into contact wit an actinomycete of the genus Streptomyces at 40°C to 55°C (p. 3234 1st column, 3rd paragraph Degradation experiments; and p. 3237 Table 3.).

Mergaret et al. therefore clearly anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (in IDS, Antonie van Leeuwenhoek, March 2003, Vol. 183, pages 183-189) and Mergaret et al. (Applied & Environmental Microbiology, 1993, Vol. 59, No. 10, p. 32388-

3238) and in view of Jendrossek & Handrick (Annu. Rev. Microbiol. 2002, Vol. 56, p.403-432) and further in view of Jarerat et al. (Macromol. Biosci., 2002, Vol. 2, p. 420-428) and further in view of Kim et al. (International Journal of Systematic Bacteriology, 1998, Vol. 48, p.59-68).

Claims 1-5 are drawn to an enzyme derived from an actinomycete of the genus Streptomyces, which is capable of degrading a polyhydroxyalkonate (PHA) resin, having a molecular weight between approximately 47,000-56,000, optimum pH of the enzyme between 4 and 10, the optimum temperature of the enzyme between 40°C and 55°C, and a method for degrading a polyhydroxyalkanoate resin, comprises causing the polyhydroxyalkonate resin to come into contact with the enzyme.

Claims 6-9 are drawn to a method for degrading a PHA resin, comprises causing the PHA to come into contact with an actinomycete of genus *Streptomyces* at 40°C to 55°C, and actinomycete of the genus *Streptomyces thermovulgaris*, *Streptomyces thermoolivaceous*, *Streptomyces thermohygroscopicus* (thermophilic *Streptomyces*).

Kim et al. (2003) teach isolating an enzyme from an actinomycete of the genus *Streptomyces*, a method for degrading a polyhydroxyalkanoate resin, comprises causing the polyhydroxyalkanoate resin to come into contact with the enzyme, the enzyme having an optimum pH between 4 and 10, and an optimum temperature between 40°C and 55°C (see Abstract and page 186, 1is column, 3rd paragraph lines 11-13, and p.184-185, 2nd column Enzyme assay).

Kim et al. (2003) further teach polyhydroxyalkanoate (PHAs) are one of the most promising candidates for use as a biodegradable material. The ability to degrade

extracellular PHA in the environment and to use degradation products as sources of carbon and energy depends on the secretion of specific extracellular PHA depolymerases. PHA-degrading microorganisms of many taxa are widely distributed in various natural environments and several PHA depolymerases have been isolated and characterized (p.183, Introduction).

Kim et al. do not teach the Streptomyces deposited under accession No. FERM BP-10158, the *Streptomyces* is *Streptomyces thermovulgaris*, *Streptomyces thermoolivaceous*, *Streptomyces thermohygroscopicus*, and *Streptomyces thermocarboxydovorans.* However, at the time the invention was made thermophilic species of Streptomyces, *Streptomyces thermovulgaris*, *Streptomyces thermoolivaceous*, *Streptomyces thermohygroscopicus*, and *Streptomyces thermocarboxydovorans* were all very well known in the art (Jarerat et al. and Kim et al. 1998).

Moreover, Mergaret et al. teach enzymatic degradation of PHA and PHBs by bacterial depolymerases, and further teach degradation of poly(3-hydroxybutyrate) and Poly(3-hydroxybutyrate-Co-3-Hydroxyvalerate) plastics in soils by *Streptomyces* species, included thermotolerant (growth at 45°C) strains (see abstract, p.3236, 2nd column lines 29-31, and p.3238, 1st column lines 1-3 and Table 3.). Mergaret et al. further teach microbial degradation is enhanced at higher temperatures and the degrading organisms comprised several gram-negative bacteria, gram-positive bacilli, streptomycetes, and molds. The latter two groups predominated at 40°C (see Abstract, Introduction, p.3237, 1st column, Conclusion, lines 13-15).

Furthermore, Jendrossek & Handrick teach isolation of PHA-degrading microorganisms and biochemical properties of extracellular depolymerases, and further teach, PHA depolymerases share several characteristics, high stability at a wide range of pH, temperature, and ionic strength, a relatively small (<70 kDa) with most depolymerases consisting of only one polypeptide, alkaline pH optimum (p.408, 3rd column, lines 6-10).

Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of Mergaret et al., Kim et al. (2003), and Jendrossek & Handrick and to screen the claimed thermophilic strains of *Streptomyces* for PHA-degradation, to isolate a PHA-degrading strain(s), and to purify the PHB-degrading enzyme from the isolated strain, to achieve the predictable result of PHA and PHB degradation. Because, at the time the invention was made screening and isolation methods to identify PHA-degrading strains were available, also as taught by Mergaret et al. PHB-degrading activity of thermophilic *Streptomyces*, were very well known, thus a person of ordinary skill in the art would have been motivated to use those methods to achieve the predictable result of obtaining a *Streptomyces* strain capable of degrading PHAs.

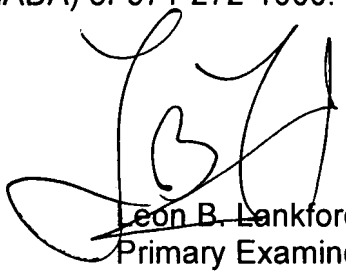
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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